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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,707	06/07/2001	Theresa M. Allen	5325-0148.34	1073

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/07/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/876,707	Applicant(s) Allen	
Examiner Gollamudi Kishore	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 8, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-32 and 57-81 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-32 and 57-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The power to inspect dated 4-2-03, the petition under 1.137 (b), the response and the filing as an RCE all dated 4-3-03 are acknowledged.

Claims included in the prosecution are 21-32 and 57-81.

Claim Rejections - 35 U.S.C. § 102

- 1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

- 2. Claims 21-25, 60 and 71 are rejected under 35 U.S.C. 102(a) as being anticipated by Torchilin (5,534,241).**

Torchilin discloses a polymer system (DTPA-polylysine) one end of which is attached to a lipid and the other to either a therapeutic or diagnostic polychelator (targeting ligand); (note the abstract, figures, columns 4-5, 9-13 and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Torchilin does not teach the targeting ligand. This argument is not found to be persuasive. Claims are interpreted in their broadest sense and instant claims recite just 'targeting ligand' and do not specify what is being targeted. In the absence of such, it could be interpreted that since the host tissues are targeted for imaging and therapy in Torchilin, 'Gd-polychelating complex' is the targeting agent.

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Claim Rejections - 35 U.S.C. § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 3. Claims 21-32 and 57-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torchilin (*5,534,241) in view of Harris (5,932,462).**

Torchilin as pointed out before, discloses a polymer system (DTPA-polylysine) one end of which is attached to a lipid and the other to either a therapeutic or diagnostic polychelator (targeting ligand); (note the abstract, figures, columns 4-5, 9-13 and claims). Torchilin also teaches the use of other targeting groups such as enzymes, lectins and antibodies in the liposomes compositions and protective polymers such as PEG (same polymer as in instant invention) on col. 2, lines 18-59 and col. 9, 34-48. Torchilin does not specifically teach that these ligands could be attached to the polymer via the activated groups instead of the polychelating ions, or in addition to the polychelating agent or on the protective polymer, PEG.

Harris while disclosing a multi-armed polymer systems containing PEG-lysine polymers teaches that the polymer functional groups could be activated to couple to various target ligands (columns 12, 26, 36, 37 and claims).

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It would have been obvious to one of ordinary skill in the art to use any targeting molecule in the polymer complex of Torchilin with the expectation of obtaining at least similar results since Harris teaches that any ligand could be coupled to the hydrophilic polymer system.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the examiner's rationale relies on the polychelating agent being a targeting moiety and therefore, must fail for that reason. This argument is not found to be persuasive. Even assuming that the polychelating agent is not a targeting moiety, However, the examiner point out that was not the rationale. As pointed out before, although Harris is directed to a polymer ligand combination, on col. 2, line 45 through col. 3. Line 20 the reference clearly teaches that polyethylene glycol (same as in instant invention) has two functional hydroxyl groups and both could be activated to react with amino groups and Harris is clearly indicative of the attachment of targeting ligands to one of the activated groups. The primary reference of Torchilin as discussed above and as recognized by applicants themselves, teaches the attachment of polyethylene glycol to the liposome surface via amino linkages on the phospholipid head group (note also col. 10, lines 15-55) and Torchilin also provides guidance to attach one end of the polymer chain to the liposomal surface and the other to the chelating ligand. It is therefore, would have been obvious to one of ordinary skill in the art from the combined teachings of Torchilin and Harris to couple a targeting ligand and the liposomal surface to PEG with a reasonable

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expectation of success. Applicant is incorrect in interpreting the examiner's position as one of substituting the targeting moiety for the polychelating compounds since Torchilin teaches the modification of the liposomal membranes using the protective polymers (such as PEG, which is the same as in instant invention) and the targeting groups in addition to the polychelating agent. This is clearly evident from col. 2, lines 18-59.

As pointed out before, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, although Harris is directed to a polymer ligand combination, on col. 2, line 45 through col. 3. Line 20 the reference clearly teaches that polyethylene glycol (same as in instant invention) has two functional hydroxyl groups and both could be activated to react with amino groups and Harris is clearly indicative of the attachment of targeting ligands to one of the activated groups. The primary reference of Torchilin as discussed above and as recognized by applicants themselves, teaches the attachment of polyethylene glycol to the liposome surface via amino linkages on the phospholipid head group (note also col. 10, lines 15-55) and Torchilin also provides guidance to attach one end of the polymer chain to the liposomal surface and the other to the chelating ligand. It is therefore, would have been obvious to one of ordinary

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skill in the art from the combined teachings of Torchilin and Harris to couple a targeting ligand and the liposomal surface to PEG with a reasonable expectation of success.

Therefore, applicant's argument that there is no suggestion to combine the references is not found to be persuasive and the rejection is maintained.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

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All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

May 2, 2003